

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE  
RENAL PHARMA LTD. and VIFOR  
FRESENIUS MEDICAL CARE RENAL  
PHARMA FRANCE S.A.S.,

Plaintiffs,

v.

LUPIN ATLANTIS HOLDINGS SA,  
LUPIN PHARMACEUTICALS, INC., and  
TEVA PHARMACEUTICALS USA, INC.,

Defendants.

C.A. No. 18-390-LPS

**[PROPOSED] STIPULATED PROTECTIVE ORDER**

**WHEREAS**, Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. and Vifor Fresenius Medical Care Renal Pharma France S.A.S. (collectively, “Plaintiffs”) and Defendants Lupin Atlantis Holdings SA and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”) and Teva Pharmaceuticals USA, Inc. (“Teva”) (collectively, Lupin and Teva are referred to herein as “Defendants”), parties to the above-captioned action (“this Action”), may seek discovery of documents, information, or other materials that may contain trade secrets or other confidential research, development, or commercial information of other parties or third parties;

It is stipulated and agreed by and between Plaintiffs and Defendants that the terms and conditions of this document shall govern the handling of documents, depositions, pleadings, exhibits and all other information exchanged by the Plaintiffs and Defendants in this Action or provided by or obtained from third parties to this Action.

**NOW THEREFORE**, pursuant to Federal Rule of Civil Procedure (“Fed. R. Civ. P.”) 26(c), upon the stipulation and consent of the parties and for good cause shown, the Court hereby **ORDERS** that:

1. **Scope of Protection:** This Stipulated Protective Order (“Protective Order” or “Order”) shall govern the disclosure, use, and production of information, documents, testimony, responses to requests for production of documents, answers to interrogatories, responses to requests for admissions, tangible things, and all other discovery taken pursuant to the Federal Rules of Civil Procedure furnished, directly or indirectly, by or on behalf of any Plaintiff, Defendant, third party or witness in connection with this Action.

2. **Designations of Protected Information:** As set forth in ¶ 2(a), any producing person, entity, or third party (“Producing Party”) may designate any information, document, testimony, tangible item, each set of interrogatory answers, each set of responses to requests for production of documents, each set of answers to requests for admission, or portion thereof, to be disclosed or produced to any other person or entity (“Receiving Party”) as “CONFIDENTIAL,” as defined below, pursuant to this Protective Order (“Protected Information”). Any copies of such materials, summaries, or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed Protected Information, and the same terms regarding confidentiality of these materials shall apply as apply to the originals.

a. Any Producing Party may designate as CONFIDENTIAL any document, tangible item, each set of interrogatory answers, each set of answers to requests for admission, each set of responses to requests for production of documents, or portion thereof, to be disclosed or produced to any Receiving Party if the Producing Party claims in good faith that such information comprises or contains non-public proprietary, confidential or commercially sensitive information, including, but not limited to, information or materials comprises or contains non-public proprietary, confidential or commercial confidential information related to: (i) New Drug Application (“NDA”) No. 205109 or Abbreviated New Drug Application (“ANDA”) No. 211386

or ANDA No. 211411; (ii) non-public correspondence with the U.S. Food and Drug Administration (“FDA”) relating to NDA No. 205109 or ANDA No. 211386 or ANDA No. 211411; (iii) the research and development of the products in NDA No. 205109 or ANDA No. 211386 or ANDA No. 211411; (iv) any other research, development, manufacture, and production of the subject matter relating to any of the patent(s)-in-suit; (v) highly sensitive financial and economic information, including financial planning, financial performance, market plans, business plans, competitive strategies, or business relationships; (vi) research, development, manufacture, and production, including current or future products, such as those presently in development or undergoing FDA approval; or (vii) patent applications that are not yet published and contain information that constitutes a trade secret. Such identification shall be made at the time when the answer to the interrogatory, response to a request for production of documents, or answer to the request for admission is served, or when the document or thing is provided to the other party.

b. All information, documents, or tangible items shall be clearly marked or stamped with the legend CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER or a suitable equivalent, prior to production to or exchange with the Receiving Party. Each page of each document produced in discovery shall, to the extent practicable, bear a prefix identifying the Producing Party and a unique identifying number. Likewise, each discrete unit of each tangible item produced in discovery shall, to the extent practicable, also bear a prefix identifying the Producing Party and a unique identifying number. When a party sends correspondence, including emails, that includes or attaches CONFIDENTIAL information, that party shall indicate prominently that the correspondence contains or is itself CONFIDENTIAL information.

c. All information to be disclosed orally (such as at a deposition), if not otherwise designated as CONFIDENTIAL during the oral disclosure (such as at the time of the

deposition), shall be automatically designated as CONFIDENTIAL for a period of fourteen (14) days after receipt of the official transcript of the deposition by counsel for the Producing Party, and the transcript shall not be disclosed during such time by a non-designating party to persons other than those persons named or approved according to ¶ 4. Thereafter, the information contained in the deposition transcript will no longer be deemed CONFIDENTIAL unless: (i) in a writing sent to counsel for the Receiving Party before the expiration of the fourteen-day period, counsel for the Producing Party claims in good faith that the deposition transcript contains CONFIDENTIAL information; (ii) at the deposition, counsel for the Producing Party states on the record that the deposition transcript contains CONFIDENTIAL information; or (iii) as provided in ¶ 9.

d. Third Parties. If discovery is sought of a person or entity not a Party to this action (“Third-Party”) requiring disclosure of such Third-Party’s CONFIDENTIAL information, the CONFIDENTIAL information disclosed by such Third-Party will be accorded the same protection as the Parties’ CONFIDENTIAL information, and will be subject to the same procedures as those governing disclosure of the Parties’ CONFIDENTIAL information pursuant to this Protective Order.

3. **Limits on Use:** Any information, document, or tangible item designated CONFIDENTIAL that is disclosed or produced in connection with this Action shall be maintained in strict confidence by the Receiving Party, and shall be used solely in connection with this Action, any appeal thereof, settlement discussions and negotiations, and any form of alternative dispute resolution in this Action, and not for any other purpose including without limitation any other legal, regulatory, commercial or business purpose, including the pursuit of intellectual property rights, or in connection with another legal, regulatory, or patent prosecution proceeding in the U.S.

or a foreign country, and cannot be used in any or cited within any citizen's petition or any other submission to FDA or other regulatory bodies, including but not limited to the United States Pharmacopeia, except by consent of the parties or order of this Court.

a. The attorneys of record for the parties and other persons receiving Protected Information governed by this Protective Order shall exercise reasonable care to ensure that the Protected Information designated as CONFIDENTIAL pursuant to this Protective Order is: (i) used only for the purposes specified herein; and (ii) disclosed only to individuals as provided for in ¶¶ 4-5 below, respectively.

b. Nothing herein shall bar or otherwise restrict counsel for a party from rendering advice to his or her client with respect to this Action, and in the course thereof, from generally referring to or relying upon Protected Information received by the party. In rendering such advice or otherwise communicating with their client, counsel shall not disclose the specific content of any CONFIDENTIAL information where such disclosure would not otherwise be permitted under the terms of this Protective Order.

4. **Disclosure of Information Designated CONFIDENTIAL:** Except as provided in ¶¶ 5 and 13 of this Protective Order, access to documents or information designated CONFIDENTIAL, shall be strictly limited to the following persons:

a. Outside trial counsel or outside attorneys of record for the parties, including partners, associates, staff and contract attorneys, and their authorized secretarial, paralegal, clerical and legal assistant and support staff who are not and will not be for the duration of two (2) years after the conclusion of this Action including appeals, involved in (1) the drafting or amendment of specifications, claims, or claim language for any patent or application owned by the party represented by counsel, in any patent office proceeding relating to iron-based phosphate

adsorbents, including processes or intermediates relating to production of products containing iron-based phosphate adsorbents (this provision shall not preclude a Receiving Party's involvement in opposition, inter partes review, or other post-grant proceedings before the United States Patent and Trademark Office ("USPTO") or any foreign patent-granting authority, provided that the Recipient is not involved in any aspect of obtaining or modifying claims, including drafting, discussing, advising on, proposing, or reviewing claims or claim amendments), or (2) the preparation or submission of any communications with the FDA or any equivalent foreign agency (including but not limited to citizen petition) that relate to the approval requirements for any iron-based phosphate adsorbents, including processes or intermediates relating to production of iron-based phosphate adsorbents, for a period of one (1) year after the final disposition or settlement of this action including appeals and petitions for review; however, nothing in this provision prevents the individual from performing work before the FDA solely for obtaining or maintaining approval of the Receiving Party's own NDA or ANDA, provided no CONFIDENTIAL information is used or disclosed.

b. the Court and Court personnel;

c. consultants or experts retained by the parties or their attorneys for purposes of this Action, who are not objected to pursuant to ¶ 6, and who first agree to be bound by the terms of this Protective Order by executing a written Confidentiality Undertaking (in the form set forth in Exhibit A hereto) prior to being provided access to CONFIDENTIAL information, and their respective staffs;

d. court reporters, translators, videographers, and their respective staffs employed in connection with this Action;

e. non-parties specifically retained to assist outside counsel of record with copying and computer services necessary for document handling, and other litigation support personnel (e.g., graphic designers and animators, database entry personnel);

f. Four (4) in-house counsel and/or personnel (and their support staff) responsible for oversight of this litigation whose duties require access to material designated CONFIDENTIAL, provided that said designated in-house counsel and/or personnel have executed a written Confidentiality Undertaking (in the form set forth in Exhibit A hereto) prior to being provided access to CONFIDENTIAL information, and the Receiving Party has received a copy of such Undertaking. For Plaintiffs, the designated in-house counsel and/or personnel shall be: Joerg Dreyhsig (Vice President, Associate General Counsel Intellectual Property, Fresenius Medical Care AG & Co. KGaA), William Leschensky (Vice President and Associate General Counsel, Relypsa, Inc.), and Others to be decided. For Lupin, the designated in-house counsel and/or personnel shall be: Dr. Himanshu Godbole (Vice - President, IPMG, Lupin Ltd.), Dr. Archana Roy (Dy. General Manager, IPMG, Lupin Ltd.), Irshad Mulani (Manager, IPMG, Lupin Ltd.) and Manish Mundra (Asso. Director, IPMG, Lupin Atlantis Holdings SA). For Teva, the designated in-house counsel and/or personnel shall be: Rivka Jungreis (Associate General Counsel) and Others to be decided. The designated in-house counsel and/or personnel are not and will not be for the duration of two (2) years after the conclusion of this Action including appeals, involved in (1) the drafting or amendment of specifications, claims, or claim language for any patent or application owned by the party represented by counsel, in any patent office proceeding relating to iron-based phosphate adsorbents, including processes or intermediates relating to production of products containing iron-based phosphate adsorbents (this provision shall not preclude a Receiving Party's involvement in opposition, inter partes review, or other post-grant proceedings before the

USPTO or any foreign patent-granting authority, provided that the Recipient is not involved in any aspect of obtaining or modifying claims, including drafting, discussing, advising on, proposing, or reviewing claims or claim amendments), or (2) the preparation or submission of any communications with the FDA or any equivalent foreign agency (including but not limited to citizen petition) that relate to the approval requirements for any iron-based phosphate adsorbents, including processes or intermediates relating to production of iron-based phosphate adsorbents, for a period of one (1) year after the final disposition or settlement of this action including appeals and petitions for review; however, nothing in this provision prevents the individual from performing work before the FDA solely for obtaining or maintaining approval of the Receiving Party's own NDA or ANDA, provided no CONFIDENTIAL information is used or disclosed. In the event that any of the aforementioned individuals cease to have responsibilities relating to this Action, Plaintiffs or Defendants respectively may designate an alternative in-house counsel and/or personnel to replace such person upon giving written notice of such change to the opposing party, identifying the counsel and/or personnel's position and responsibilities. If the party receiving a notice designating in-house counsel objects to the designation, such party shall make its objections known to the sender of the notice in writing within seven (7) business days of receipt of the written notification. Such objection must be for good cause and state with particularity the reasons for the objection. If the parties are unable to resolve their objections, the party seeking to make the disclosure may apply to the Court to resolve the matter. If a written notice of objection is provided, no CONFIDENTIAL information shall be disclosed to the designated in-house counsel until the objection is resolved by an order of the Court or by an agreement among the parties involved;

g. Any person who is providing testimony, in the course of such testimony, provided that the person confirms that he or she will comply with any confidentiality obligations



he or she currently has to the Producing Party under preexisting agreements, if (i) the witness is listed as an author, addressee, or recipient on the face of the document designated CONFIDENTIAL to be shown to the witness or is identified in prior discovery or by the witness in his or her deposition as an author or recipient of the information, with the understanding that this paragraph does not preclude a Party from bringing a motion in the future for a protective order to bar another Party from showing a particular witness CONFIDENTIAL information; (ii) the CONFIDENTIAL document was produced by or obtained from said witness or the witness's employer, and the witness has knowledge of such information as indicated by foundational testimony or otherwise, even if not an actual recipient of the document at issue; (iii) the parties stipulate to allow the deponent to review the document; or (iv) upon Order of the Court for good cause shown;

h. Mock jurors and/or judges engaged by any party or consultant in preparation for trial, provided they acknowledge that the information they are shown shall be kept confidential and sign Exhibit A attached hereto.

5. **Disclosure to Author or Recipient:** Notwithstanding any other provisions of this Protective Order, nothing herein shall prohibit counsel or a party from disclosing a document containing Protected Information designated CONFIDENTIAL to any person who appears from the face of the document to have drafted, prepared, executed, or received the document. This Protective Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether the witness authored or previously had access to or knowledge of CONFIDENTIAL information.

6. **Presence of Authorized Persons:** For deposition and trial testimony, unless modified by agreement of counsel or Court order, only those persons authorized by this Protective

Order to receive CONFIDENTIAL information may be present during those portions of a deposition and trial which may require the disclosure of CONFIDENTIAL information.

7. **Identification and Disclosure of Experts or Consultants:** If any party desires to disclose another party's Protected Information designated CONFIDENTIAL to any expert or consultant pursuant to ¶ 4(c) above, it is permitted to do so only after:

a. The party must identify in writing to the attorneys for the Producing Party each such expert or consultant. The identification of an expert or consultant shall include: (i) the full name and professional address and/or affiliation of the proposed expert or consultant; (ii) the proposed expert's or consultant's current curriculum vitae; (iii) a list of the individual's qualifications, including all publications within the last ten (10) years; (iv) any prior or current employments or consultancies for any party within the last five (5) years; (v) a list of the cases in which the expert or consultant has testified at deposition, at a hearing, or at trial within the last four (4) years; and (vi) a completed and signed Undertaking in the form of Exhibit A attached hereto from the expert or consultant. To the extent any of items (iii)-(v) are fully disclosed in the curriculum vitae provided under item (ii) of this ¶ 7(a), such items need not also be disclosed in a separate form.

b. The attorneys for the Producing Party shall have a period of seven (7) business days of receiving such notice to object to disclosure of such information to any of the experts or consultants so identified. Any party that fails to object within seven (7) business days of receiving such notice shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert for purposes of ¶ 4(c). If, during the seven (7) business days, the party giving notice receives a written objection from the Producing Party stating the specific bases for objection, there will be no disclosure of CONFIDENTIAL

information to the individual identified in the notice except as agreed by the parties or by further order of the Court. The parties shall attempt to resolve any such objection by meeting and conferring in good faith within five (5) business days of receipt of the written objection, in accordance with ¶ 6(g) of the Scheduling Order in this Action. If the objection cannot be resolved within five (5) business days of receipt of the written objection, the parties may present the dispute to the Court in accordance with ¶ 6(g) of the Scheduling Order in this Action. If relief from the Court is not sought within the above five (5) business days, the objection shall be deemed to have been withdrawn. The party objecting to the disclosure of CONFIDENTIAL information to the expert or consultant identified will be considered “the party seeking relief” in accordance with ¶ 6(g) of the Scheduling Order in this Action, and the other party will be considered “the party opposing the application for relief” in accordance with ¶ 6(g) of the Scheduling Order in this Action.

8. **Designation of Documents Under Seal:** If CONFIDENTIAL information of a Producing Party is to be filed with this Court in connection with any proceeding in this Action, it shall be filed under seal pursuant to the procedures set forth in the Court’s rules, the Court’s Scheduling Order, and the District of Delaware CM/ECF User Manual (Revised May 2018).

9. **Challenge to Confidentiality:** A Receiving Party’s acceptance of material designated CONFIDENTIAL by a Producing Party shall not constitute an admission, or create an inference, that the material is in fact confidential within the meaning of Federal Rule of Civil Procedure 26(c)(1). This Protective Order shall not foreclose any party from seeking and obtaining, on an appropriate showing, such additional protection with respect to the confidentiality of documents or other discovery materials as that party may consider appropriate. Nor shall any party be precluded from: (i) claiming that any matter designated hereunder is not entitled to the

protections of this Protective Order; (ii) applying to the Court for an Order permitting the disclosure or use of information or documents otherwise prohibited by this Protective Order; or (iii) applying for a further Order modifying this Protective Order in any respect. No party shall be obligated to challenge the propriety of any designation, and failure to do so shall not preclude a subsequent challenge to the propriety of such designation. On any challenge to the designation of any information, the burden of proof shall lie with the Producing Party to establish that the information is, in fact, CONFIDENTIAL information. If a party seeks declassification or removal of the confidentiality designation of any particular items, the following procedure shall be utilized:

a. The party seeking such declassification or removal shall give counsel of record for the Producing Party written notice thereof specifying the designated information as to which such removal is sought and the reasons for the request;

b. Counsel for the Producing Party shall respond in writing to such objection within five (5) business days, and shall state with particularity the grounds for asserting that the document or information is CONFIDENTIAL. If no written response is made to the objection within five (5) business days, the challenged designation will be deemed to be void.

c. If the Producing Party makes a response within this time period to such objection asserting the propriety of the designation, the parties will meet and confer in good faith within five (5) business days after the Producing Party's receipt of such notice in an effort to resolve the disagreement, in accordance with ¶ 6(g) of the Scheduling Order in this Action; and

d. If, after conferring, the parties cannot reach agreement concerning the matter within five (5) business days after the Producing Party's receipt of the notice, then the parties may present the dispute to the Court in accordance with ¶ 6(g) of the Scheduling Order in this Action. The document or information that is the subject of the filing shall be treated as

originally designated pending resolution of the dispute. In any motion challenging the classification, the Producing Party shall have the burden of establishing the need for classification as CONFIDENTIAL.

10. **Inadvertent Failure to Designate:** If a Producing Party inadvertently fails to designate the information as CONFIDENTIAL at the time of oral disclosure or production, the Producing Party may thereafter make a designation pursuant to this Protective Order by serving notice thereof in writing, accompanied by substitute copies of each item, appropriately designated, which shall then be deemed to be subject to the terms of this Protective Order. The receiving party shall then destroy all copies of the inadvertently or unintentionally produced CONFIDENTIAL information. Should any CONFIDENTIAL information hereunder be disclosed to any person not entitled to receive the same hereunder, then the parties intend to have such person be automatically bound by this Protective Order, and such person shall be informed within five (5) business days of the discovery of such disclosure of the provisions of this Protective Order by the Receiving Party, and the Receiving Party shall exercise all reasonable efforts to have such person sign an Undertaking in accordance with ¶ 4 above and in the form of Exhibit A attached hereto. The parties shall exercise all reasonable efforts to retrieve any such information disclosed to persons not authorized to receive the information under this Protective Order. Nothing herein shall prevent the Producing Party from applying to the Court for further or additional relief.

11. **Inadvertent Production or Disclosure of Privileged or Otherwise Protected Information:** If a Producing Party inadvertently produces information, documents, or tangible items in this Action that should have been withheld subject to a claim of attorney-client privilege, work-product immunity, or any other applicable privilege or immunity (“Inadvertently Produced Discovery”), such production shall not constitute a waiver of any claim of attorney-client privilege,

work-product immunity, or any other applicable privilege or immunity for such information, provided that, upon learning of the inadvertent disclosure, the Producing Party promptly sends to each Receiving Party a good-faith written representation that such production was inadvertent, requests return or destruction of the inadvertently produced or disclosed document or thing, and specifies the type of privilege asserted. Immediately upon receipt of this written request, the Receiving Party shall treat the document or thing in accordance with Fed. R. Civ. P. 26(b)(5)(B), and shall within five (5) business days of receiving such a request destroy or return to the Producing Party all such documents and things identified by the Producing Party as being privileged or work-product and as having been inadvertently produced. With respect to documents and things generated by a Receiving Party subsequent to the inadvertent disclosure, which documents and things contain information derived from such inadvertently produced documents and things, the Receiving Party shall within five (5) business days of receiving such a request either destroy all such derivative documents and things or redact from them all such derivative privilege or work product information in a manner such that the derivative information cannot in any way be retrieved or reproduced.

a. If the Receiving Party wishes to contest that any such document or thing was inadvertently produced or is protected by the attorney-client privilege or by work-product immunity, the Receiving Party shall so notify the Producing Party in writing on or before the date when the document or thing is due to be destroyed or returned to the Producing Party.

i. Within five (5) business days after receiving such notification, the Producing Party shall provide to the Receiving Party for each such document or thing a description consistent with Fed. R. Civ. P. 26(b)(5)(A)(ii) of the basis for the claim of privilege or immunity.

ii. Within five (5) business days after the Receiving Party receives such description from the Producing Party, the parties will meet and confer in good faith in accordance with ¶ 6(g) of the Scheduling Order in this Action, and, failing resolution, the parties may present the dispute to the Court in accordance with ¶ 6(g) of the Scheduling Order in this Action. If the dispute is presented to the Court, the Producing Party shall have the burden of proving that the documents and things in dispute are protected by the attorney-client privilege or by work-product immunity. Pending the Court's ruling, the party challenging the assertion shall continue to treat the documents and things in dispute in accordance with Fed. R. Civ. P. 26(b)(5)(B).

12. **Other Proceedings:** By entering this Protective Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Protective Order who becomes subject to a motion to disclose another party's designated CONFIDENTIAL information pursuant to this Protective Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed. If any documents, tangible things, or information received under this Protective Order and in the possession, custody, or control of any Receiving Party is sought by subpoena, request for production of documents, interrogatories, or any other form of discovery request or compulsory process, including any form of discovery request, the Receiving Party to whom the process or discovery request is directed shall, unless otherwise precluded from doing so by law or court order, (i) within ten (10) business days after receipt thereof, give written notice by hand, e-mail, or facsimile of such process or discovery request together with a copy thereof, to counsel for the Producing Party; (ii) cooperate to the extent necessary to permit the Producing Party to seek to quash such process or discovery request; and (iii) not produce or disclose the

documents, things, or information until the Producing Party consents in writing to production or the Receiving Party is ordered by a court of competent jurisdiction to produce or disclose the documents, things, or information, so long as the order is not stayed prior to the date set for production or disclosure. Nothing herein shall prevent timely compliance with a governmental subpoena or court order.

13. **Prior or Public Knowledge:** The restrictions and obligations set forth in this Protective Order shall not prohibit discussions with any person or entity regarding any CONFIDENTIAL information if said person or entity already has legitimate possession thereof. The restrictions and obligations set forth in this Order relating to CONFIDENTIAL information shall not apply to any information that: (i) is already public knowledge; (ii) has become public knowledge other than by disclosure by a Receiving Party; (iii) has come or hereafter comes into the Receiving Party's legitimate possession without any confidentiality restrictions and independently of the Producing Party; or (iv) is released from being designated CONFIDENTIAL, by the Producing Party or by order of the Court.

14. **Non-Party Material:** The terms of this Protective Order, as well as the terms of any other protective order that may be entered into between a discovering party and non-party for the production of information to the discovering party, are applicable to Protected Information provided by a non-party in connection with this Action. Information provided by a non-party in connection with this Action and designated CONFIDENTIAL pursuant to the terms of this Protective Order shall be protected by the remedies and relief provided by this Protective Order.

15. **Return or Destruction of Designated Information:** Within sixty (60) days after final termination of this Action, including any appeals, unless otherwise agreed to in writing by an attorney of record for the Producing Party, each party shall assemble and return, or destroy and



certify destruction of, all materials containing information designated CONFIDENTIAL, including all copies, extracts and summaries thereof, to the party from whom the designated material was obtained, except that: (i) any documents or copies which contain, constitute or reflect attorney's work product or attorney-client privilege communications; (ii) all pleadings, motion papers, correspondence, expert reports, written discovery responses, deposition transcripts, deposition, hearing and trial exhibits, and court-filed documents; and (iii) all Outside Counsel's electronic files other than the production of documents and things may be retained by counsel, subject to a continuing obligation to protect all such material pursuant to this order. The fulfillment of the obligations imposed by this paragraph, whether by return, destruction, or both, shall be certified in writing by the Receiving Party. All obligations and duties arising under this Protective Order shall survive the termination of this Action. The Court retains jurisdiction indefinitely over the parties, and any persons provided access to CONFIDENTIAL information under the terms of this Protective Order, with respect to any dispute over the improper use of such CONFIDENTIAL information.

16. **Return or Destruction of HIPAA Information:** Notwithstanding the foregoing, a Receiving Party may not retain an archival copy of any documents for which the Producing Party has notified the Receiving Party that such documents contain information protected by the Health Insurance Portability and Accountability Act ("HIPAA"). Accordingly, within thirty (30) days after final termination of this Action, including any appeals, a Producing Party shall identify all exhibits containing information protected by HIPAA that are contained within deposition transcripts, deposition exhibits, Court transcripts, Court exhibits and other submissions to the Court. Within thirty days of receipt of such identification, the Receiving Party shall either return

to outside counsel for the Producing Party or destroy such exhibits and certify in writing to outside counsel for the Producing Party.

17. **Waiver or Termination of Order:** No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for each Producing Party, or by an Order of the Court for good cause shown. The restrictions provided for herein shall not terminate upon the conclusion of this Action, but shall continue until further Order of the Court.

18. **Modification of Order:** This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties without further Order of the Court. The Court retains jurisdiction even after the termination of this Action to enforce this Protective Order and to make such amendments, modifications, deletions and additions to this Protective Order as the Court may deem appropriate.

19. **Prior Production:** To the extent that the parties have produced documents prior to the entry of this Protective Order under Del. LR 26.2, those documents will be treated as having been produced marked “CONFIDENTIAL” within the scope of this Protective Order, unless specifically indicated otherwise.

Dated: January 22, 2019

/s/ Brian E. Farnan

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Plaintiff Teva Pharmaceuticals USA, Inc.*

Dated: January 22, 2019

SO ORDERED this \_\_\_\_\_ day of \_\_\_\_\_, 2019.

\_\_\_\_\_  
United States District Judge

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE )  
RENAL PHARMA LTD. and VIFOR )  
FRESENIUS MEDICAL CARE RENAL )  
PHARMA FRANCE S.A.S., )

Plaintiffs, )

v. )

C.A. No. 18-390-LPS

LUPIN ATLANTIS HOLDINGS SA, )  
LUPIN PHARMACEUTICALS, INC., and )  
TEVA PHARMACEUTICALS USA, INC., )

Defendants. )

**AGREEMENT TO BE BOUND BY STIPULATED PROTECTIVE ORDER**

I, \_\_\_\_\_, state that:

a. My present employer is \_\_\_\_\_ and my  
present work address is \_\_\_\_\_.

b. My present title, occupation, or job description is  
\_\_\_\_\_.

c. I have read and understand the provisions of the Stipulated Protective  
Order entered in this Action and I will comply with the provisions of that Stipulated Protective  
Order. I consent to be subject to the jurisdiction of this Court for enforcement of this Stipulated  
Protective Order.

d. I will hold in confidence and not disclose to anyone not qualified under  
the Stipulated Protective Order any CONFIDENTIAL information, or any summaries, abstracts  
or indices of any CONFIDENTIAL information, that is disclosed to me or that I prepare.

e. Upon conclusion of the above-captioned Action, including appeal, I will  
return all CONFIDENTIAL information – and any summaries, abstracts and indices thereof, and

documents or materials that I received or prepared relating thereto – in my possession to outside counsel for the party for whom I was employed, retained or acted as witness.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: \_\_\_\_\_